Values, Hopes and Concerns

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VALUES, HOPES, AND CONCERNS

Report on the 'GET: Social Values Project' for the
Advisory Commission on Regenerative Medicine and Cellular Therapies
(and invited participants)

PROJECT OVERVIEW

Title
Governing Emerging Technologies: Social Values and Stem Cell Regulation in Argentina

Principal Investigator
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Collaborating Investigator
Fabiana de Arzauaga

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£74,771 – ***Economic & Social Research Council*** (No. RES-000-22-2678)

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SCRIPT, AHRC Research Centre in Intellectual Property and Technology Law
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Project Description
The GET: Social Values Project is an ESRC-funded project intended to explore how social and ethical values are, and can be, translated into legal rules. It is examining the conduct and motivating values of Argentine stakeholders as they work to formulate socially acceptable regulatory structures in this field. Objectives include (1) mapping the most salient features of the social/moral/legal debates, (2) developing dialogues with stakeholders to reveal the multiple goals envisioned for regulation, and (3) contributing to the debate surrounding, and formulation of, value-sensitive regulatory models.

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Further Information
See http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/ and http://www.esrcsocietytoday.ac.uk/.

Acknowledgements
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Project Outputs (To Date)

Papers

S. Harmon, "Emerging Technologies and Developing Countries: Stem Cell Research (and Cloning) Regulation and Argentina" (2008) 8(2) *Developing World Bioethics* 138-150.

S. Harmon, "Hidden Battles and Stem Cell Research in Argentina: A Response to Salles and Luna", forthcoming in *Developing World Bioethics*.

S. Harmon, "Regulation of Stem Cell and Regenerative Science: Stakeholder Opinions, Plurality and Actor Space in the Argentine Social/Science Setting", forthcoming in *Law, Technology & Innovation*.

S. Harmon, "Ambition and Ambivalence: Encouraging a 'Techno-Science Culture' in Argentina Through Engagement and Regulatory Reform", submitted to *Studies in Ethics, Law & Technology*.

Policy Briefs & Reports

S. Harmon, G. Laurie & F. Arzuaga, "Report: Regulation of Clinical Research Involving Stem Cells: Towards the Construction of a Regulatory Model for Argentina Learning from the Experiences of the United Kingdom" (2007).

S. Harmon & G. Laurie, "The Regulation of Human Tissue Use and Regenerative Medicine in Argentina: Making Experience Work" (2008) (Available at http://www.mincyt.gov.ar/index.php?contenido=comision_celulas_madre).

S. Harmon, "Risk, Innovation, Diversity, Complexity: Policy Options and Objectives for Stem Cell Regulation" (2008) (Available at http://www.mincyt.gov.ar/index.php?contenido=comision_celulas_madre).

S. Harmon, "Regenerative Medicine Governance: Report of the Workshop on Governance of Research Using Human Embryonic Tissue" (2009) 6:3 SCRIPTed 729-740.

Presentations

S. Harmon, "Innovation, InnoGen and Argentina", for Argentine Science & Technology Agency, "Regulation of Clinical Research Involving Stem Cells", International Policy Conference, 29-30 November 2007, Buenos Aires.

S. Harmon, "Governing Emerging Technologies: The Regulatory Model and Social Values Underlying Stem Cell Governance in Argentina – A State of Flux", for 4S & EASST, "2008 Annual Meeting", 20-23 August 2008, Rotterdam.

S. Harmon, "Governing Emerging Technologies: Social Concerns, Social Values and Argentine Regulatory Instruments in the Stem Cell Arena", for PRIME-Network, "Europe-Latin America Conference on Science and Innovation Policy", 24-26 September 2008, Mexico City.

S. Harmon, "Governing Emerging Technologies: Project Overview and Core Regulatory Issues" for Argentine Advisory Commission on Regenerative Medicine & Cellular Therapies, "Second International Conference on the Regulation of Stem Cells and Human Tissue", 14 October 2008, Buenos Aires.

S. Harmon, "Stem Cell Research and Social Values: Evidence from Argentina" for National Cheng Kung University, 4 February 2010, Tainan.

Posters

S. Harmon, "Regulatory Models for Emerging Technologies: Stem Cell Research Regulation in Argentina and the UK", presented in Exeter, UK, in January 2007, Calgary, Canada, in November 2007, and Edinburgh, UK, in April 2008.

S. Harmon, "Argentina Unbound: Governing Emerging Technologies: Social Values in Stem Cell Regulation in Argentina", presented in Edinburgh, UK, in March 2008 and March 2009.

S. Harmon, "Stem Cell Research: Values, Objectives & Issues Poster Series" (9 Posters), presented in Buenos Aires, Argentina, in August 2009 (at the Advisory Commission's "Regenerative & Cellular Sciences: Values, Objectives & Issues for Implementation", Workshop), and presented in Cardiff, UK, in October 2009, and Edinburgh, UK, in March 2010.

Planned Future Outputs

S. Harmon, F. Arzuaga & G. Laurie, "Regulating for Uncertainty: The Challenges of Foresighting in New Technologies" in preparation. (paper)

S. Harmon & F. Arzuaga, "Health Research Governance in Argentina: Current Context and Objectives for New Regulation" in preparation. (paper)

S. Harmon, "Rights, Values, Research and Human Health: Evidence from Argentina" for World Medical Association's 18th World Congress on Medical Law, "Health, Law and Ethics at the Outset of the Third Millennium", 8-12 August 2010, Zagreb. (presentation)

S. Harmon, "Ethical Values and Stem Cell Governance: Perceptions of Values Amongst Argentine Stakeholders" in preparation. (paper)

FORWARD PLAN

Both the PI and Co-I as well as others associated with the GET: Social Values Project found the collaboration very fruitful and fulfilling, and the evidence generated very interesting and useful. Opportunities for continued socio-legal research in Argentina are being pursued:

1. **GET: Ideas Project:** The PI will submit a proposal to the ESRC under its Follow-On Funding scheme, which provides funding for up to one (1) year's work pursuing dissemination and research impact for a pre-existing project.

2. **Practical Ethics Project:** The PI, Co-I and other partners from the University of Edinburgh and FLACSO will submit a proposal to the Wellcome Trust to conduct further research in Argentina on the practical understanding and use of ethics by a range of stakeholders, including the public and church.

3. **Further Research & Networking:** The August 2009 interactive workshop highlighted a range of issues which require further attention by policy stakeholders or further research. We hope to secure funding to undertake small and medium projects to address some of these issues, and to consider them in the broader Latin American and international contexts.

PROJECT METHODOLOGY

The GET: Social Values Project was designed with the intention of gathering qualitative data around key issues of bioscience, and in particular stem cell research governance, in Argentina, the objective being to discover stakeholder values relevant to, and objectives for, this science and its governance.

While the data generated by the 22 semi-structured interviews cannot be said to represent the Argentine view – the subject sample was too narrow and too small for such claims – it captures important qualitative evidence of the views of key stakeholders in the field.

Prior to commencement, the GET: Social Values Project was subject to institutional ethics review and then funding body ethics evaluation. Research participants were chosen from the medical, scientific, academic, policy, legislative and regulatory communities.[*] As the project was never intended to be a public engagement mechanism, the opinions of the broader public were not solicited. Rather, those originally viewed as most likely to influence the nature and content of bioscience and stem cell regulation were targeted (ie: Argentine science policy elites), for, it was felt, only by targeting those most engaged in the pre-legislative process could we measure the existence of functional connections between values and objectives, on the one hand, and legal outputs (when they emerge), on the other.

Following preliminary research, semi-structured interviews lasting 50 to 90 minutes were conducted. Each interview was, with permission, recorded. Open-ended questions and an informal interview schedule were used to encourage participants to speak in their own words about their experiences, observations, opinions, and desires. Transcription of the interviews was performed within the PI's host institution and that work was subject to a Confidentiality Agreement. Anonymised transcripts were shared between the PI and the Co-I. Every line of transcription and interviewer notes was coded and analysed for emergent themes, and evidence (responses) relating to those themes were grouped together, ultimately forming four primary themes, each of which were subdivided into subtopics. The whole assessment was refined through an iterative process, thus enabling different interpretations to be incorporated.

The structure of the evidence is therefore as follows. Summaries of the evidence under each category are attached as Appendices.

Theme 1 – Mapping the Landscape

Category 1.1: Stated understandings of the existing science setting in Argentina
Category 1.2: Stated understandings of the existing regulatory setting in Argentina

Theme 2 – Social Context

Category 2.1: Opinions about the perceived social costs and benefits of stem cell research
Category 2.2: Information about past or existing public debates on SCR (or public understanding)
Category 2.3: Views on hurdles to achieving (moral) regulation given conflicts of values and objectives

Theme 3 – Regulatory Ambitions

Category 3.1: Opinions on the necessity of government regulation in SCR
Category 3.2: Opinions on the appropriate purposes and objectives of regulation
Category 3.3: Views on the influence of the global nature of science and the value of the UK model

Theme 4 – Social/Moral Values Held

Category 4.1: Views about the appropriate source of moral values
Category 4.2: Values considered to be the most important for inclusion within regulation
Category 4.3: Opinions on how research regulation might address moral concerns

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[*] The investigators interviewed at least one respondent, but often multiple respondents (some with overlapping roles), from each of the following categories: national-level politician; national regulatory agency member; national advisory committee member; medical clinician, medical researcher, basic scientist, ethicist, academic lawyer.

PROJECT EVIDENCE & CONCLUSIONS

Summary Conclusions

Although the GET: Social Values Project has now concluded, it is, in some ways, premature to speak of 'conclusions'. While themes and categories have been identified, concepts and their relationship to theory (if any can be articulated) are still being explored. Moreover, the GET: Social Values Project was very much preliminary, and our view is that theoretical saturation has not been achieved (ie: more data ought to be collected with respect to our emerging categories and concepts so as to better illuminate them). Having registered those important caveats, we offer the following conclusions and observations:

Category 1.1: Most respondents took a positive view of research capacities and trends in Argentina, though there was concern around 3 issues: (1) an inability to get a clear picture of the research environment due to lack of oversight/reporting; (2) unethical and/or unauthorised research that was known to be undertaken; and (3) the sustainability of quality research given a training environment that was persistently shuttered and undemocratic.

Category 1.2: Most respondents felt there was very little in the way of research regulatory architecture, and most felt this was a sub-optimal situation, despite the dangers in Argentina of trying to democratically create a new research framework (either general or bespoke to stem cells).

Category 2.1: Everyone conceded the financial costs associated with stem cell research, and most felt it was a cost worth bearing despite Argentina's other pressing social and health conditions. Some also identified social disruption as a cost, but felt that the potential benefits outweighed them.

Category 2.2: Most respondents had very little knowledge of any public debates on stem cell research beyond their own activities, which were mostly restricted to professional circles. They all felt that public understanding of stem cell and related research practices and (realistic) objectives was very low. They did not equate these low science literacy rates with resistance to science, and indeed generally felt that people were very positive about science and research.

Category 2.3: The primary hurdles to achieving (moral) regulation were identified as: (1) low science literacy amongst legislators and the public; (2) an absence of opportunities to engage with the broader public (and develop science democratically); and (3) the dogmatic position of the church toward science and its undue political influence.

Category 3.1: All respondents felt that the current regulatory situation was far from ideal, and all felt that something should be done to improve it, but there was no consensus on the best way forward. (This is an area where further evidence would be useful, including broader public evidence.)

Category 3.2: While opinions on the appropriate objectives of regulation varied, all respondents felt that law had an important role to play in directing the new and powerful biosciences (including stem cell research). The most commonly cited objective for research regulation was to (1) create a positive science environment, (2) ensure professional (and

international) standards, and (3) protect patients.

Category 3.3: All respondents were aware of the importance of international science and standards to the development of science and science expertise in Argentina. With respect to the UK model of stem cell research regulation, most acknowledged it as good and world-leading, but most also felt that, while certain of its elements and processes might be adopted in Argentina, it could certainly not be imported unchanged.

Category 4.1: Generally, it was felt that religion (and certainly formal religious or Church positions) was *not* an appropriate source of moral values. Sources sited as valuable and legitimate were international legal and bioethics instruments, the community, and the individual properly informed about the science possibilities and competing ethical issues. (This is an area where it would be valuable to generate further and more specific/detailed evidence.)

Category 4.2: Most respondents felt that broad social/moral values must be reflected (if not explicitly identified and defined) in research and clinical regulation. The values considered to be important by respondents include human wellbeing, solidarity, justice, democracy, knowledge, autonomy, dignity, honesty, safety, scientific freedom, professionalism, transparency, and population health. (This is an area where it would be valuable to generate further and more specific/detailed evidence.)

Category 4.3: Opinions on this issue varied widely, with a common position being no opinion at all, though some suggestions were offered (and are summarised in Appendix 4).

Key Observations and Recommendations

In addition to the above category-specific conclusions, we observed the following issues, which we believe are of key importance and are amenable to specific recommendations:

Engaging with Values

Observation: While respondents could articulate some core values, many did not define those values very explicitly or clearly, perhaps because while they may feel shaped and/or guided by them, these values are not regularly at the forefront of their thoughts. As such, some had difficulty exploring them beyond short labels, which they (often correctly) assume pass enough information to be comprehensible. As a result, the extent to which, and length at which, respondents engaged with our values questions, and were able to discuss and express them beyond catch-phrases was, to some extent, profession-dependent (with the ethicists and philosophers being the most articulate). Indeed, there was a view among some non-scientists that scientists have no real knowledge about ethics. Almost no respondents were prepared to talk in any detail about how ethics works in guiding science in Argentina, or, more importantly, about what ethical process (ie: or analytical framework) was needed in moving forward. It would seem from this that no sophisticated framework for assessing options and determining boundaries is regularly applied. However, all respondents expressed a keen interest in participating in boundary discussions, both within science and policy networks (if they should emerge, and many hoped they would), and more broadly. *Recommendation:* Achievable, concrete and sustainable efforts should be undertaken by the MOST, in cooperation with the Ministry of Health (and perhaps under the guidance of the Advisory Commission) to enhance networks and foster a closer interdisciplinary science/policy/ethics community in the broad regenerative research and medicine field. Such a network would encourage dialogue and idea-exchange, and would better prepare (and fortify) science protagonists to engage with broader publics, which was widely identified as being

important for the long-term prospects of stem cell research and science more generally.

Evidence from Publics
Observation: As suggested by many of the respondents, there is a need in Argentina for more research on the public's views about (1) the value of science, (2) the values people hold in respect of science or which are implicated by science, and (3) appropriate boundaries for science (or alternatively, an appropriate means of setting boundaries on an ongoing basis for science). Associated with this, there was a desire for more opportunities to think about these questions in the context of specific practices. *Recommendation:* See the recommendation above, which should include the hosting of regular interdisciplinary interactive international workshops.

Boundaries for Science
Observation: Most of the *researcher* responses reflect a mild to strong aversion to (moral) limits being put on science, in part because of morality's entanglement with a politicised church position in Argentina and a cynicism toward same. However, *all respondents* exhibited a strong interest in opening up possibilities for science in Argentina, and in having morally justified articulated. *Recommendation:* The importance of (good) science governance cannot be overestimated. We are in a knowledge-based century and a bio-economy. What is decided for science will have consequences for the economy, healthcare, individual and community wellbeing, commercial structures and behaviours, and the way knowledge-creation is undertaken. The MOST and Ministry of Health, together with other related national bodies need to come together in the fashioning of a broad science and research policy (as it relates to health), and begin working toward a more explicit, joined-up, rational governance framework.

Research v. Clinical Practice
Observation: While the 2007 and 2008 conferences held in Buenos Aires suggested a loose consensus around separating the research and clinical settings, conceptually and regulatorily, almost every respondent identified 'patient safety' as an important concern in the research setting. In short, in practice, perhaps because there is a keen awareness for the need for research to improve clinical practices and outcomes, there was a distinct collapsing of fields. *Recommendation:* If different regimes are created, donor, subject and patient safety must be a key component for both, and clinical safety should be in the forefront of all researcher thinking from a very early stage, which may require a re-emphasis of researcher training.

Policy Actors – The Church
Observation: Though it may be less directly influential on society and the way people behave in their personal lives, the church is centrally important to Argentine politics and to formal dialogues on bioscience research in Argentina. However, the role of the church was almost universally seen as problematic and its position as negative (hypocritical, counter-productive, generally contrary to the good development of science and Argentina). *Recommendation:* This is a particularly challenging cultural factor with which science protagonists must contend. Generally, the church must either be engaged with, perhaps through further socio-legal research intended to identify greater common ground and flexibility, or, if the goal is to maximise science potential and permit the open conduct of research in quickly moving fields, the church must be circumvented.

Other Policy Questions
Other policy-related questions that emerge as a result of this research include the following:

- Given the importance of (international) research collaboration to Argentina, the governance of

Material Transfer Agreements and of the import/export of cell lines is critical. How does the current regulatory framework address these issues and does it need to be clarified?

- Given the international nature of research, and the suggestion (by some respondents) that unethical research was taking place in Argentina, good management practices for labs is an important issue. How does the current regulatory framework address this issue and does it need to be revisited (so as to authorise the inspection of labs and revocation of research funding where breaches are identified)?

- Given the current state of Argentine research governance, local structures and oversight are key. Are there any standards being set for IRB members and is there any training or standardisation of responsibilities being devised? (Presumably Argentina wishes to 'stamp' research outputs with oversight that is internationally accepted.)

- The IP-early and IP-heavy model of commercialisation (developed by the pharma, petro-chem and auto industries) is being applied to all sectors of innovation. How can or should Argentina respond to that model? Are any macro-debates about commercialisation and the ethics of commercialisation in the bioscience and health research settings being planned?

- Given the entanglement of health and healthcare improvement, on the one hand, and bioscience development, on the other, health actors have an interested in innovation despite often working to different timescales. Do the Ministries of Science and of Health see their policy bailiwicks as integrated and what forms of collaboration and cooperation are emerging?

APPENDIX 1

PROJECT EVIDENCE
THEME 1 – MAPPING THE LANDSCAPE

Category 1.1: Stated Understandings of Existing Argentine Science Setting

Perhaps unsurprisingly, most respondents adopted a favourable view of the biosciences generally (as a valued undertaking), and an almost equally favourable view of the technical state of the biosciences (and particularly stem cell and reproductive research) in Argentina. For example, respondents stated:

- Despite having less funds than Brazil, Argentina has a good history of basic science.
- A growing number of groups are conducting research in stem cells, some coming from gene therapy, and some 9 different institutions had some 14 projects.
- Argentina has 30 accredited IVF centres doing good work, and the quality of reproductive practitioners in Argentina is good.
- Argentina has good research experience and resources, and is in a position to advance synthetic biology and pharmacology.
- FLENI and the Leloir Institute are doing good basic research on adult stem cells and imported embryonic stem cells.

However, respondents were also critical in many respects, stating as follows:

- There are PIs operating who are not aware of standards.
- Hospitals are using cellular therapies for everything and using protocols with no authority from the Ministry of Health or INCUCAI.
- The power of the church influences what we know about what people are doing (ie: dogma instils silence and secrecy; in the embryology context, diagnostic tests are performed but not disclosed, indicating hypocrisy).
- The quality of information-transfer and instruction is not good, and, as a result, the next generation of scientists may not be as good as the present group.
- There is a deficit of strong ideas in science at the moment.

Respondents stated that the general landscape would benefit from the following:

- Argentina does not need every science, but it needs an open environment where researchers can exchange opinions.

- Stem cell science needs clusters of organisations and international collaborations

- Regenerative medicine requires new hypotheses and new models, and lots of work on stem cells from different sources before safe use.

- There is inadequate support for clinical trials, and Argentina is behind the rest of the world in that regard, so it needs to expand the remit of research funding.

Category 1.2: Stated Understandings of Existing Argentine Regulatory Setting

While there was some hesitation by some respondents on this issue, most were well aware of the very little regulation that exists in Argentina on the issue of stem cell research regulation. Most felt that no regulation existed governing (non-clinical) stem cell research, and that what is not specifically forbidden is permitted. It was generally understood that:

- Cloning has been banned (1997 Decree).

- A 2004 Resolution offers guidance for cord blood banks and describes how to establish GMP quality programmes (basically translating international standards set by FACT).

- IVF remains unregulated (and although practitioners follow AMA guidelines, different centres have different policies (eg: on cryo-preservation) so standard practices do not develop.

- Cell lines can only be bought with Ministry of Health permission.

- INCUCAI deals with clinical trials using stem cells (or stem cells being put into patients), and Resolution 1490 sets standards for evaluating clinical trials protocols.

- A Committee in the Ministry of Health deals with any protocols over which INCUCAI is unsure.

- ANMAT is the equivalent of the US FDA and applied its own guidelines to research protocols, and it is the only body entitled to conduct inspections, but it is not involved with basic (non-clinical) research.

- The Advisory Commission on Regenerative Medicine & Cellular Therapies (under the Ministry of Science), and Committee on Clinical Trials (under the Ministry of Health) are advisory only.

However, with respect to stem cell research more specifically, and especially that at the basic (non-clinical) level, there was a feeling that:

- there is a lack of clarity as to who is in charge and the law is lagging behind;

- consent and confidentiality are important, but communication of science issues is lacking;

- IRBs have control or responsibility, but IRBs are poorly trained and supported, and are unaware of appropriate standards;

- individual professional codes are helpful, as are US NIH and international guidelines, but the system is very unsystematised and bureaucratic, with a lot of political movement (eg: there are new projects or proposals in the Congress all the time, and it is difficult to keep track), and no institutional continuity, and not enough technical knowledge within relevant institutions; and

- because anyone can currently work in stem cells, there is no good knowledge of who is ethical and who is unethical.

One respondent felt that the remit of the Advisory Commission needed to be widened so as to better govern this area.

APPENDIX 2

PROJECT EVIDENCE
THEME 2 – SOCIAL CONTEXT

Category 2.1: Opinions on Social Costs and Benefits

There was less evidence on this issue, and it was very uniform, but also quite interesting, as people drew on past experiences to interpret what is happening and what might happen.

On the issue of costs, all respondents recognised that stem cell research is an expensive undertaking, and so there are financial costs, and decisions have to be made about where to put research and clinical funds, bearing in mind the many (and often more pressing) problems that Argentine society faces. Other costs noted by respondents were as follows:

- Cost: The pressure on science to deliver within a much-hyped environment and poor public understanding.

- Cost: The potential to develop treatments that will help more foreigners than locals, and the IVF setting was noted, where people come to Argentina for cheaper, high-quality treatment.

- Cost: The potential to alienate those who are strongly opposed to the science, and thus fracturing society (ie: social costs), a cost which could be minimised through information, but some people will not accept it regardless of information, and they are in power positions.

However, most respondents agreed that state funded research is important, that building knowledge is important, and that stem cell research represented a great opportunity for science and for cures, and therefore to alleviate suffering. Benefits that were specifically identified include:

- Benefit: This research is for the future, but that a more immediate benefit is building research strength.

- Benefit: Stem cell research may allow Argentina to generate a platform to help Argentina benefit from therapies and keep in touch with developments in clinical regenerative medicine, and there is a positive history in biomedicine so expect positive developments.

On a cautionary note, one respondent admitted that benefits are difficult to foresee, saying that gene therapy was to be the end-all but it failed.

Category 2.2: Information about Past Debates and Public Understanding

This emerged as one of the most important issues. Each respondent's evidence is summarised:

R1: People are not qualified to talk about certain things; religious institutions are strong in Argentina and faith is important, so it is important to split religion between church on one hand and personal convictions on the other, b/c they may not agree

R2: The influence of researchers is important and the science groups and medicos are talking about stem cells. There is some debate in National Congress. No macro framework for debate and no public debates yet.

R3: There is some media noise around stem cells, but mostly negative impact because it increases expectations. Some patient groups have influence in the Senate. Science not high on the public agenda, and assume ESCR is a no-flyer.

R4: There were some debates when Dolly was born, but nothing since other than at the Advisory Commission. We are still debating the importance of science more generally in Argentina. Discussions with people suggest that have gut feelings against ESCR, but none have said it should be forbidden.

R5: Need debate but haven't had broad debate yet. Had a debate on umbilical cord blood banks in Congress, and a new Bill on clinical trials. Minister of Science wants to regulate use of human cells for research purposes, but no action yet

R6: No real public debates and people are not well informed; there has been no wide, specific, well-informed discussion with all stakeholders.

R7: Not aware of public debates.

R8: Has spoken about stem cells, and there's a lot of bad information out there. There have been some debates about the origin of stem cells within the Association of Catholic Doctors.

R9: Not aware of any debates, but people need to discuss the science before they need it. Whenever embryos are raised there is a fear that the abortion debate will be opened (abortion illegal but genetic diagnosis practiced), so if SCR is tied to IVF there will be trouble. The relationship between scientists and public is not good.

R10: Held a small bioethics conference on SCs a few years ago in national Academy of Medicine. Some media coverage in last 5 years and also in science circles. Would like to call for debate but there doesn't seem to be a big demand in the Argentine public.

R11: Scientists have mostly been ignored in the legislative efforts to date; some social debate around SCR is needed but it is not on government agenda.

R12: Some universities have post-grad courses and hospital IRBs discuss the issue, but they do not communicate to the wider public. There is some public discussion about embryos, but not as a source for stem cells; there were 3 moments when this topic was discussed openly – (1) abortion and the contraception campaign; (2) day after pill; (3) cord blood resolution – but no serious discussion in society and no consensus.

R13: Some public debates but not good quality because people are not talking about issues; no real

information is given to people because of fears of negative repercussions so researchers do not engage.

R14: Took part in some international debates and made representations in Brazil, Uruguay and Europe, but cannot do so in Argentina because camps are diametrically opposed with the religiously influenced opposed to science.

R15: Involved in public debates around the world, but in Argentina voices are isolated and people are cautious. SCR will not be the issue that causes people to rise up and be heard because there are more pressing issues, but with good information and work, public support can be developed.

R16: There have been some debates on IVF and embryos, but none on stem cells. There are science community meetings that agree that SCR is important but there is a problem with religion. Did one session with the public, given lectures at Parliament and have made representations through the TV and magazines (Pariti).

R17: Have spoken with Parliament, the Advisory Commission, other researchers, and friends, but not with the general public; have heard some reports in the media but no debates; the science community needs to find a place to talk about research and SCR.

R18: Have not participated in specific events but have discussed SCR at IRB. Have received questions from public in course of work, and feel that the general public has a solidarity toward one another and have expressed a willingness to allow cells to be used in research.

R19: Have made representations to Parliament, and, through a consortium, have communicated to individual members of the public about the need for stem cells.

R20: Not much is said about SCR in Argentina and there is a reluctance to discuss it in formal environments. Context is very important and key words can be used to make an impact on people, or to close down a willingness to understand. There are few debates other than within MOST. There is support for debate, as evidenced by Interactive Workshop, but how will it be initiated? What mechanisms?

R21: Public opinion is hard to say; only limited discussion on the status of the embryo and use of spare embryos; church opposes all uses and IVF so no real debate, just a few opinions of the church while researchers talk about freedom of research – talk past each other.

R22: Debate is taking place at elite science levels, in science and ethics groups, but not in public.

Category 2.3: Views on Hurdles to Moral Regulations

Respondents had very strong and overlapping views about the primary hurdles to realising a sound and moral research governance framework in Argentina. Key ideas that emerged under this heading are as follows:

- Definitions: Defining the moral and immoral is very difficult, so arriving at 'moral' standards is a problem.

- Religion: Morality and morals are all too often confused with religion; boundaries of science must be defined by objectives, not religious principles. There is silence around issues like reproduction, which has a certain social taboo because associations of infertility with sin, so people misunderstand reproductive and regenerative medicine. While the Church is less influential on the public mind, it is still strategically placed politically.

- Public Institutions: Propaganda is a problem; superstitions are given as certainties and actors are not concerned with telling the truth. The media was criticised for the way it reports about science and its regulation, and for its conservatism. So were public institutions, with one respondent indicating that Argentineans are not given the space for good, free moral discussions, they do not believe in institutions, and they are not optimistic about what government can achieve, so they are sceptical about regulation.

- Hypocrisy: Too often, people think X in private but remain silent in public and acquiesce with Y, or they think X in their heart but say nothing and permit Y because they don't want to disturb the status quo.[1] So it is difficult to determine how genuine opinions are.

- Public Expectations: Public expectations create pressure and tensions which makes good regulation difficult to achieve. Expectations must be modified to better reflect current understandings (which are early stage in many cases). It was felt that the tone of discussions created impatience, and people need to realise this science is about the future.

- Absence of Debate: It is hard to base regulation on an evidence base because there is very little (social) evidence,[2] and there is a lack of science communication and researchers are failing to pass their knowledge (and enthusiasm) on to the public. There is a gap between science and societal understanding.

- Scientific Pace: The speed at which science is raising and answering questions (but mostly raising questions) makes good regulation difficult to achieve. Science and scientific techniques are evolving all the time.

- Political/Regulatory Division: There is a need for better debate between the National Ethics Committee, the Ministries, the Advisory Commission, etc., and these bodies need to be in contact concerning funding so all projects are ethical regardless of who is funding them.

- Commerce: The role of commercial interest shapes how people think and act, and is often not worried about moral issues.

- Competition: It is dangerous to use science as a means of becoming a leader because feelings of inferiority in Argentina might lead people to do 'whatever it takes'.

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[1] One respondent claimed that many Catholics divide themselves into a professional person and a private person, and this allows them to act in certain settings, such as IVF.

[2] One respondent stated that, if you do not have good groundwork through good public communication, it will be difficult to form the consciousness of the people and make good law; things in Argentina are often delayed too long and then explode.

APPENDIX 3

PROJECT EVIDENCE
THEME 3 – REGULATORY AMBITIONS

Category 3.1: Opinions on Necessity of Regulation

This evidence was very interesting. All respondents agreed that the present situation with respect to research regulation (of stem cells and regenerative medicine research) was not ideal, but respondents did not agree on how to address the situation. The evidence coalesced around four (4) primary options:

Option 1 - No Law: Those in this camp were sceptical about the government's ability to arrive at a good, rational law in this area. Opinions were as follows:

R1: There needs to be communication between the Ministries, but don't need big structures nor stem cell-specific instruments. A law on stem cells may be too specific.

R16: The tendency is to ban so having a law could be bad; better to have no law than bad law, and implementation is a problem. I would like to see regulations from an agency; rules made by thinking people who respect freedom.

R18: Not sure if Argentina needs regulation, but it is important to have good lab practices.

R21: Regulation would be premature because Argentina has not had proper debates, and science literacy in Congress is low. I would prefer a commission to adopt regulations, offer opinions and review cases. This would be more flexible and allow ranking of alternatives.

Option 2 – Some Law: Another group felt something was needed but couldn't say what might work. There was a general concern about the translation of research to the clinical setting:

R3: Science-to-clinic needs a strong regulatory framework. It is critical to have governance of the clinical setting. The current situation not best.

R4: Argentina does not need a specific stem cell Protocol, but need INCUCAI to take the lead where patients are involved, and need a law on obtaining samples for research.

R5: Need to avoid giving doctors chance to falsely do things; need regulation

R20: Regulation is necessary, but I am sceptical about the possibility and can see why some say 'leave it alone'.

Option 3 – A General Research Law: The largest group of opinions felt that a general law which

addressed a number of core issues in research and clinical research was warranted, and that it needed to be accompanied by debate:

R6: Argentina needs clarity of regulatory authority. Government has no idea of the details and needs technical people to ID weaknesses and assess details. Argentina needs to erect good lab practices, IRB training programmes, better ethical training for researchers, and work needs to be done in the provinces, which have less knowledge than the feds.

R8: Law is important, especially when it comes to translating science into humans. A general law is OK.

R9: Science and law should work together, become better acquainted, and professional associations need to monitor activity, ensure discussion, and work toward fair treatment and honesty.

R10: Role of law in science is very important. Regulation is needed because of the power of the new sciences. We need consultation and care to protect human dignity, which is a difficult notion that needs to be talked about.

R11: Law needs to regulate scientific practice, but it needs to be rational, not emotional.

R12: Don't need a specific regulation but something which addresses research with medical consequences; a law which rules medicine beyond ANMAT.

R14: Argentina should have regulation of research and new technologies related to reproduction.

Option 4 – A Stem Cell Law: This last group felt a stem cell specific law was OK:

R2: The stem cell situation needs order. There is currently confusion, which puts good researchers in the same light bad ones. Researchers are pushing for governance to stop others doing and saying things that are not true.

R15: Ideally, stem cell research would be regulated in Argentina, but we need to walk some steps first, including being more honest in certain issues, including abortion.

R17: The Constitution says embryos are persons, but a law is needed to say whether we can work with embryos. We can't work well without regulation; researchers and doctors need guidance.

R19: A regulation dedicated to stem cell research might improve budgets, but need a law dedicated to all aspects of this science: stem cells, induced pluripotent stem cells, therapeutic cloning.

Category 3.2: Opinions on Purposes/Objectives of Regulation

There was extensive evidence given on this point, with a lot of overlap in opinions. Basically, it was felt (by at least one respondent in each case) that a law in this area (whether a stem cell law or something broader) should address the following issues; the law should:

- highlight the utility of science and the need to promote wellbeing and alleviate human suffering;
- define science and articulate conditions which encourage ethical and open science, taking a

holistic view from basic science to clinical treatment so that useful science is promoted and regulatory complexity and overlap is avoided;

- define key terms such as 'pre-embryo', 'embryo', 'foetus', 'benefit', etc., and state whether human tissue is a drug, device or treatment/process, and in doing so it must reflect scientific facts (as we know them);[3]

- contain clear rules and boundaries about where tissue can be sourced from, what can be done with tissue, etc., and boundaries must be informed by moral and ethical values;[4]

- address other important research subjects such as:

    - individual autonomy and donor/subject informed consent;
    - dignity and privacy and confidentiality of personal data;
    - donor/subject (and ultimately patient) safety;
    - equal access to the benefits of research;
    - permitted and prohibited practices, including reproductive and therapeutic cloning;
    - establishment of local ethical/oversight frameworks;
    - emphasis of internationally-informed operating standards;
    - payment for tissue, and conditions (and duration) of tissue retaining;
    - role of commercial companies and position of commercial cell lines;
    - patenting and researcher access to resources;
    - tissue, organ and resource sales;
    - researcher conflicts (and sponsor-PI relationships);
    - specific issues around international collaborations (and their promotion).

- include local oversight and monitoring and sanctions for breach of conditions, standards or values so as to protect patients and public health, and to avoid scientific fraud;

- contain technique-specific regulations which can be more easily changed so as to keep pace with fast moving technologies and practices, and thereby promote progressiveness and flexibility, and these regulations could create subject- or area-specific agencies who undertake oversight, inspection and enforcement of standards.

A strong strain throughout all of the evidence was that, even if a purely research was adopted, it must be aware that research is ultimately directed at discovering clinical treatments and so human and patient safety must ALWAYS be at the forefront.

It was also felt that, with respect to clinical trials, there was a need to emphasis and enforce international standards; several respondents intimated that they were aware of unauthorised clinical trials, so there is a need to coordinate international standards better.

Respondents also addressed the issue of technologies moving and evolving quickly, and generally agreed that this caused there to be a lot of unknowns which meant that the law (or regulatory

[3] Two respondents cautioned that human tissue and embryos have symbolic value, so rather than focus on 'embryos as persons', the law should acknowledge that value and, within that context, identify what can be done with it and what conditions should be placed on its use.

[4] While there was not unanimity on this point, the majority of respondents felt that the claims of evolved humans outweigh those of the unborn/embryo, and that claims must be weighed using criteria which must be explicit.

framework) must be flexible and inclusive so as to capture new practices. This fast evolution, which often precedes regulation, also means that there should be good science communication and debate so as to promote approaches which recognise Argentina's pluralist society.

Category 3.3: Opinions on Influence of Global Science and Value of UK Model

Respondents felt that most researchers travel and get ideas from around world, so there are US and EU influences in the science being undertaken in Argentina. Generally, science is global and Argentina follows trends like everyone else. It was felt that some elements of this science, including tissue and cord blood banking, needed to focus on the international element because they only work efficiently if they are networked internationally.

With respect to this internationalisation on the issue of standards, it was stated that Argentine researchers generally follow a range of international discipline-specific guidelines, so their standards are international, but they are self-imposed and not well (or not at all) policed.

On the issue of the UK model, while it was generally recognised as being internationally leading, there was scepticism that it would work or should be adopted in Argentina. Key arguments were:

- There is no IVF law in Argentina so regulating stem cells through a fertility framework is not ideal; better to do it through the Ministry of Science.

- Argentina needs a PROCESS like in the UK (open and with an independent authority), but might decide to go in a different direction, not least because of the future of stem cells, one assumes, is not in reproduction.

- Looking at the UK, Spain, Canada, and New Zealand is OK, but Argentina needs to adjust those models for its cultural setting

APPENDIX 4

PROJECT EVIDENCE
THEME 4 – SOCIAL / MORAL VALUES

Category 4.1: Views on Appropriate Source of Moral Values

The evidence on this issue suggested a deep scepticism toward religion and a strong doubt that it could have a positive impact. Generally, respondents felt that the core moral/social values that informed the science, its regulation, and its ethical evaluation should come from the following sources:

- the Hippocratic Oath;
- moral theory, including from Hegel and Kant, which is based on rationality and common sense;
- academic scholarship concerning justice and risk;
- international human rights ideas;
- spiritual writings (but not religious dogma).

Ultimately, however, the importance of values and of ethics is that they require us to think *deeply* about society's wellbeing, so these sources are still essential, and slogans and dogmas need to be avoided.

One respondent noted that humans are connected in a broad and loose way, not a small and close way, so individual judgments and communities are important in serving as a source. Similarly, another respondent stated that, in Argentina, as elsewhere, there are two carriers of values: (1) the public, which is largely invisible but very real; and (2) institutions, which are public but not as strongly identified with by people.

These social sources need to be consulted so as to generate good evidence and understanding. Of course, the danger is that lawmakers could say 'no' to a particular type of research, but then that is at it should be; limits must come from outside of science.

Category 4.2: Values Considered to be Most Important

No single value was claimed as important by every respondent, although patient safety (as matters moved to the clinical setting) was widely deemed to be extremely important, and scientific freedom was also widely claimed as important. Some of the key moral values that were claimed, which arguably fall under three broad headings, include the following:[5]

[5] It should be noted that, in some few cases, respondents were very specific about the name of the value and its content. More often than not, the following values are my names/characterisations and they are filled by my organisation under these names of the content of the respondents' responses.

Values For and About Society

- Human Wellbeing: Everything depends on human health. It is important to protect life, health, and wellbeing, both physical and psychological. Given this imperative, the restrictions placed on the pursuit of improving human wellbeing should be minimal. Wellbeing implies that good health is more important than long life.

- Solidarity: This value focuses on social contacts, interconnectedness, emotional ties to others, and the common good. It reminds us of our obligations to take care of people and help those in a weaker position to have some possibilities and to live with freedom. It makes 'public ethics' important, which means we should measure the value of actions by how well they avoid selfish ends and generate social benefit (ie: are directed at solving society's problems).[6]

- Justice: This value embodies equality and equity. It demands the protection of the rights and wellbeing of the weak or vulnerable and the just sharing of benefits throughout society (ie: the benefits of research must be made available and optimised).

- Democracy: This is an encompassing value that has several facets revolving around engagement, participation, contribution, and societal control. Democracy, as a moral concept, encourages participation in law-making and boundary-setting and trajectory-determining (ie: good science needs more than just scientists, who have vested interest, thinking about science). Democracy also embodies open debate and idea-exchange.[7] It recognises that no one has the absolute truth – neither science, nor religion, nor philosophy – and that governance efforts must recognise this while at the same time providing limits. Third, democracy acknowledges (and values) plurality, which is a reality in Argentine society. Given this, there must be a minimum level of liberty to act independently so long as others are not injured. Finally, democracy encourages accessibility of the governance framework (ie: the regulatory environment should not be too complex or rigid).[8] Valuing democracy means developing a common value-based or ethical language derived from communication so that values and trajectories and boundaries can be explored.

- Knowledge: Knowledge is a value in itself, and needs to be generated within moral bounds, but in doing so, it is appropriate to push boundaries (and science has done in the past). As part of this, although arguably a separate value, creativity is very important; innovations in ways of thinking and opening up new pathways for creative thought.

Values Relating to All Individuals (Scientists, Patients, etc.)

- Dignity: This is a broad and diffuse value which seeps into all others in some way. Generally, it was felt that we must recover the notion of the importance of humanity and of respecting people and frailties and vulnerabilities and potentialities. It requires a balancing of research with other values, always being careful not to instrumentalise people (you can advance science a lot when you sacrifice principles).

- Autonomy: This is based on free will, self-rule, and the creation of space for people to make decisions about themselves and for themselves. People must be allowed to act in accordance

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6 One respondent referred to Jewish religion and its admonition to do what is necessary to save others.

7 One respondent stated: "I love discussion and want to open up the ideas of the people."

8 One respondent suggested the need for something like Asimov's 3 rules of robotics, which were short, pithy, readily comprehensible, and offered a clear ranking which facilitates decision-making.

with their feelings and desires. Thus, donors, subjects and patient must receive adequate *information* so they can weigh options and make an informed decision (to *consent* to certain courses or refuse certain courses), and it imposes on others the responsibility to hold personal information in confidence and to protect the *privacy* of others. It also grounded the idea that people should retain control of their body and their body parts and products.

Values Relating to Science

- Honesty: Researchers and physicians must be honest with patients, about patients, with research data, and they must not promise to do one thing and then do another. Researchers must avoid hyperbole and inflated claims.

- Safety: Donors, subjects and patients must be protected from harmful actions. They must not be put at undue risk, and they must not be sold treatments that are not proved (eg: do not abuse patients but rather protect patients and research subjects). This value is closely allied to non-maleficence (do no harm) and beneficence (actively do good), and it encourages us to avoid unnecessary risks, manage acceptable risks, and improve the quality of life of people.[9]

- Scientific Freedom: This is the idea that a society must recognise some minimum level of liberty to act (and conduct research) in accordance with your own feelings and values so long as others are not injured. This is important in a plural society.[10]

- Professionalism: Researchers have a responsibility take opportunities and push boundaries, but in the understanding that they have responsibilities to society and to good science, and therefore they must rely on, and generate, good evidence (eg: scientific veracity), and they must abide by research and clinical standards and further develop them. This value also has risk minimisation and respect for boundaries elements.

- Transparency/Trust: This value imposes on researchers the need to be open about what they are doing and what they hope to achieve. Publics (and donors, subjects and patients) have the right to know what is behind the research Patients have the right to know the scope and purpose of research, research risks, benefits and expectations, researcher conflicts, and what is behind the research (ie: the source and provenance of tissue sources). Research must be transparent, its governance must be transparent, researchers should be called upon to defend and/or explain their work, and they should be expected to record and make public their work. All of this will promote public trust.

- Population Health: In undertaking their activities, researchers must take into account the very important issue of public and population health. This value requires a greater connection to be made between research and clinical use (ie: research actions must have some public or population utility).[11]

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[9] One respondent also referred the safety of animals and the need to avoid unnecessary use of, and harms to, research animals.

[10] One respondent stated: "If God made us, He gave us intelligence to research medicine and to improve our situation, and therefore it is important for researchers to have freedom to develop science."

[11] One respondent argued that Argentina cannot compete economically with other countries so it needs to use funds in wise ways to develop experience and translate research into clinical uses. Another respondent stipulated, for example, that researchers in the reproductive field have a responsibility under this value to ensure the birth of a healthy baby that is not compromised. I concede that this may not be an uncontroversial claim.

Although not everyone addressed this, several respondents argued that ethics is absolutely fundamental insofar as it encourages us to consider consequences of actions and therefore options. A general rule is useless because in every situation you must have the ability to rank values (absolutes are unhelpful). Additionally, 'values' were considered to be better than 'principles' because they were viewed as less rigid and more able to engage with what makes a thing morally relevant. Finally, concern was expressed that we need to be careful about how we acknowledge something as a valid 'moral' opinion; in order to arrive at valid moral opinions, we need to have moral conversations with a variety of actors. Ultimately, morality is a social conclusion for which there is no universal; it is temporally and geographically framed and it evolves. As such, the ranking of the above values is a social enterprise which requires debate. This has not yet happened in Argentina, but the results of that debate is important to any law that might follow.

Category 4.3: Opinions on How to Achieve Moral Regulation

While one respondent saw no need for the law to specifically address norms because they are already defined in the Constitution, this was not the general consensus.

It was more widely felt that legislative and regulatory (or governance) efforts must acknowledge and accommodate or reflect these key values, not only through research regulation, which should contain the key words, but also through funding frameworks and local control (or IRB training and operations).

However, there was much uncertainty as to how to ultimately achieve moral regulation. Some general strategies articulated included:

- identifying the values in the preamble of the law;
- making sure values are implicated unavoidably in the law's application;
- encouraging more contact between scientists and regulators, domestically and internationally;
- encouraging dialogue, educating people, and promoting the acceptance of obligations and compassion.

One respondent emphasised that we must not think of setting boundaries as 'stopping science' in the abstract, but rather as stopping scientists, as human beings, from doing something we feel is not appropriate, just as we prohibit people from committing murder.

Other respondents stated that specific scientific practices should not be avoided based on moral opinions alone, but only where moral opinions are in conformity with the opinions and desires of patients, doctors, officials, etc.; it must all be dynamic and frequently revisited because even morality changes.